

K080182

5. 510 (k) Summary

APR - 8 2008

Submitter of 510(k): Wieland Dental + Technik GmbH & Co. KG
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Date of Summary: 2008-01-07

Trade name: ZENO PMMA DISC

Classification name: Temporary crown and bridge resin
Product code: EBG
C.D.R section: 872.3770
Classification: Class II

Legally marketed
equivalent device: VITA CAD-TEMP FOR INLAB, MODEL, VX59-4002, VX59-4

510(k) number: K 070991

510 (k) Summary

Device description

ZENO PMMA Discs (A3/B1) are milling blanks composed of hot cured polymethyl-methacrylate (PMMA). They are intended to be used by professional dental technicians for making long-term temporary crowns and bridgeworks for the sole use of particular patients.

ZENO PMMA Discs can be machined in all machines of the ZENO Tec system. The manufacturing process of the long-term temporary crowns and bridges consists of different steps. At first the model has to be scanned. In the next step, the restoration has to be designed virtually with the help of the CAD technology. Thereafter, the realization of this design has to be carried out by the CAM technology. In a final step the restoration can be individually characterised with dental veneering composites for improving the aesthetics and it can be pre- and high shine polished.

The ZENO PMMA Discs are offered in two different shades (A3, B1) and thicknesses.

Recommended application

With the introduction of the ZENO PMMA Discs, Wieland Dental+Technik offers to the customer for the ZENO TEC System the possibility of producing long-term temporary crowns and bridgeworks with one or two pontics. These could be used, for example, with patients who should receive an implant -supported restoration, in which the long-term temporary restoration has a prophylactic function to prevent any change of the position of the abutment-teeth. In addition, the teeth are protected by the restoration against the influence of bacterial, toxic as well as thermal effects. Furthermore, it becomes possible to check the occlusion, the phonetics as well as the aesthetics.

Comparison with the predicate device

ZENO PMMA Discs are substantially equivalent to the dental device VITA CAD-TEMP. Both devices are acrylate polymers and have identical indication for use, comparable physical, biological, and chemical properties and the same prophylactic, diagnostic and aesthetic function.

Due to the high polymerization grade and excellent material properties of the ZENO PMMA Discs, the restorations possess a high-level safety and effectiveness. ZENO PMMA Discs therefore are as safe, as effective, and performs as well as or better than the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Gerhard Polzer, Ph.D.
Director Regulatory Affairs
Wieland Dental + Technik GmbH & Company KG
Schwenninger Straße 13
D-75179 Pforzheim,
GERMANY

Re: K080182
Trade/Device Name: ZENO PMMA Disc
Regulation Number: 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: January 18, 2008
Received: January 25, 2008

Dear Dr. Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

11.8. Indication for use statement

Indications for Use

510(k) Number (if known): K090182

Device Name: ZENO PMMA Disc

Indications for Use:

ZENO® PMMA Discs are milling blanks consisting of polymethylmethacrylate. They are designed for making long-term temporary crown and bridge work and have to be machined with the CAD/CAM technique. ZENO PMMA Discs are recommended for manufacturing substructures of single tooth and bridgework with one or two pontics.

C

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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(Posted November 13, 2003)